Enforcement Report - Week of April 29, 2020

Class II Drugs Event

Event ID:
85323

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/22/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Yusef Manufacturing Laboratories, LLC
Freeport West, F-4, #3
Clearfield UT United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
PEPPERMINT LIP MOISTURIZER (oxybenzone (4%) and Octinoxate (7%) SPF 15, 4.2 g tube, labeled as a) Bimark Inc., bimark.com; b) NOCO TRAIL REPORT, www.NoCoTrailReport.org; c) Herbruck's, d) St. Mark's Outpatient Surgery Center, 1250 East 3900 South Suite 100, Salt Lake City, UT 84124, e) Trust Company Oklahoma, trustok.com, f) Creekside Dental, www.creeksidedentalkennewick.com, g) Children's Healthcare of Atlanta Hughes Spalding, h) Great Smiles Orthodontics, Dr. Savage & Dr. Weissman, Crestline. Inverness.Turssville, www.bracebygreatsmiles.com, i) Acceleration station, j) The Children's Therapy & Learning Center, www.childrenstlc.com. FLAVORED LIP MOISTURIZER (oxybenzone (4%) and Octinoxate (7%) SPF 15, 4.2 g tube labeled as a) Gregory P. Miller DDS FAGD, 1140 South Avenue North Mankato, MN 56003, www.gregmillerdds.com, b) Shelby, c) Carolina Custom Traders, Wake Forest, North Carolina, c) Palm Springs Dental Associates Jonathan W. Preble, DMD, 499 E. Central Parkway, Suite 200, Altamonte Springs, FL 32701, www.drjpreble.com. LIP MOISTURIZER (oxybenzone (4%) and Octinoxate (7%) SPF 15, 4.2 g tube labeled as Family Dental of Thronton, 12889 Quebec St, Thornton, CO 80602, www.FamilyDentalofThornton.com.

Product Quantity:
12,983 tubes

Reason for Recall:
Superpotent drug: This lot of SPF containing lip balm contains up to 150% of the label claim for active ingredient Oxybenzone.

Recall Number:
D-1251-2020

Code Information:
Lot #: 14381, Exp. Date 9/2023

Class II Drugs Event

Event ID:
85357

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/17/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Therapeutics, LLC

11960 Sw 144th St
Miami FL United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr), 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC Miami, FL 33186, NDC 68968-5552-3

Product Quantity:
7957 30-count boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1247-2020

Code Information:
Lot: 86647 Exp. 09/2020

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 20 mg over 9 hours (2.2 mg/hr) 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC Miami, FL 33186, NDC 68968-5554-3

Product Quantity:
5,614 30-count boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1248-2020

Code Information:
Lot: 86354 Exp. 08/2020

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC Miami, FL 33186, NDC 68968-5555-3

Product Quantity:
14,142 30-count boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1249-2020

Code Information:
Lots: 86355 Exp. 07/2020; 86356 Exp.08/2020; 86550 Exp. 07/2020; 87348 Exp. 01/2021; 87965 Exp. 01/2021

Class II Drugs Event

Event ID:
85487

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Nationwide with the United States and Puerto Rico.

Associated Products

Product Description:
Cefixime for Oral Suspension USP, 100mg/5mL, Rx Only, Manufactured for: Lupin Pharmaceutical, Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Mandideep 462 046 INDIA, NDC 68180-405-01

Product Quantity:
4,518 bottles

Reason for Recall:
Subpotent Drug: low out of specification (OOS) test result observed in long term stability study.

Recall Number:
D-1252-2020

Code Information:
Lot #: F800779, Expiry 4/2020

Class II Drugs Event

Event ID:
85511

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed Nationwide in the United States.

Associated Products

Product Description:
Lisinopril Tablets USP, 20 mg, 1000-count bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore MD 21202, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775, India. NDC 68180-0981-03

Product Quantity:
11,808 bottles

Reason for Recall:
Product Mix-Up: a complaint received indicating mix-up of 10 mg Lisinopril tablets inside of 2 sealed bottles of 20 mg/1000 count bottles.

Recall Number:
D-1250-2020

Code Information:
Lot # Q000255, Exp 01/2022